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10/583,751

04/03/2007

Bharat Raghunath Char

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EXAMINER

COUNTS, GARY W

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,751	<b>Applicant(s)</b> CHAR ET AL.	
	<b>Examiner</b> GARY W. COUNTS	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-16,20 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12-16,20 and 22-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/28/10 has been entered. Currently, claims 1, 3-10, 12-16, 20 and 22-27 are pending and under examination.

### **Withdrawn Rejections**

2. All rejections of claims not reiterated herein, have been withdrawn.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 1, 4, 5, 7-10, 16, 20 and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rech-Weichselbraun et al (US 2004/0171087) in light of Sawyer et al (US 5,602,041) and in view of Mitoma (Patent Abstracts of Japan, 63111467, 1988)(submitted in IDS filed 04/03/07) and further in view of Gatto-Menking et al (US 2003/0108973).

Rech-Weichselbraun et al discloses a ready-to-use solid support, kits and methods of making and using the solid support. Rech-Weichsebraun et al disclose preparing microtiter plates (solid support) for use in detecting analytes in a sample (abstract, pgs 1-4). Rech-Weichselbraun et al disclose precoating the wells of the microtiter plate with antibody (abstract, para 0001, 0050-0053) specific for the analyte of interest. Rech-Weichselbraun et al disclose contacting the plate with a first antibody and washing with buffer such as phosphate buffer saline (e.g. para 0053-0054). Rech-

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Weichsebraun et al disclose blocking the plate by the addition of phosphate buffer saline (stabilizer) and bovine serum albumin (para. 0056). As shown by Sawyer et al ('041) blocking reagents (stabilizers) such as bovine serum albumin and fish gelatin provide for stabilizing the specifically bound biomolecules and prevent denaturation that can result in loss of immunological or enzymatic activity (e.g col 1, lines 13-42). Rech-Weichsebraun et al disclose removing excess blocking reagent (stabilizer) (e.g. para 0059). Rech-Weichsebraun et al disclose drying the plate with a circulating drier (air-drying) (e.g. para 0059). Rech-Weichsebraun et al disclose that the wells of the plate additionally comprise the detection reagents in lyophilized form and disclose that mixtures of the detection reagents are added to the well and lyophilized (e.g. para's 0031-0035, p. 4). Rech-Weichsebraun et al disclose that the detection reagents can be a detection antibody (second antibody) and an enzyme-coupled antibody (third antibody) against the detection antibody (e.g. para 0046). Rech-Weichsebraun et al disclose storing the solid support and components in a kit (e.g. abstract, para 0029, pgs 3-4). Rech-Weichsebraun et al disclose that the microtiter plate can comprise polystyrene (para. 0048). Rech-Weichsebraun et al disclose the solid support can be used in ELISA methods for the detection of an analyte in a sample (e.g. para 0035, pgs 4-7). Rech-Weichsebraun et al disclose reconstituting the plates with distilled water (e.g. pgs 4-7) and adding sample, incubating, washing, adding substrate and photometrically detecting the complexes (e.g. pgs 2-7). Rech-Weichsebraun et al discloses that the analyte can be proteins, steroids, chemical compounds, drugs, nucleic acids and similar substances (e.g. para. 0045).

Rech-Weichsebraun et al differs from the instant invention in failing to teach incubating the stabilizer at a temperature of 4 degrees Celsius. Rech-Weichsebraun et al also differs from the instant invention in failing to explicitly teach the precoated antibody is a monoclonal antibody. Rech-Weichsebraun et al also fails to explicitly teach storing in a sealed package.

Mitoma teaches that it is known and conventional in the art of immunoassays to add bovine serum albumin blocking reagent (stabilizer)(same reagent as used by Rech-Weichsebraun et al) and incubate the blocking reagent (stabilizer) in the well at a temperature of between 2-25 degrees Celcius. Therefore, with respect to the 4 degree Celcius as recited in the instant claims, the optimum temperature for the blocking reagent (stabilizer) in the incubation step can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation.” Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation .” Id. At 458,105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

Gatto-Menking et al teaches that it is known and conventional in the art to immobilize monoclonal antibodies to solid supports and utilize the monoclonal

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antibodies for the specific detection of analytes such as proteins (e.g. para. 0045-0046). Gatto-Menking et al also teaches sealing components and containers and teaches that this provides for protection of the reagents and containers from exposure to contamination by air or moisture (e.g. para's 0065-0066).

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to incorporate monoclonal antibodies such as taught by Gatto-Menking et al into the solid support and modified methods of Rech-Weichsebraun et al because Rech-Weichsebraun et al is generic with respect to the antibodies to be used as capture antibodies and Gatto-Menking et al teaches that it is known and conventional in the art to incorporate monoclonal antibodies to provide for the specific detection of analyte such as proteins (same analyte as disclosed by Rech-Weichsebraun et al.

With respect to claims 23-27 as instantly recited Rech-Weichsebraun et al specifically teaches an embodiment wherein the microtiter wells comprise the first, second and third antibodies (see teachings supra) and specifically teaches that the second antibody (detection antibody) is specific for the analyte and teaches that the third antibody is labeled with enzyme and that this third antibody is specific for the detection antibody (see e.g. page 4, para 0046 "enzyme-coupled antibody against detection antibody"). Thus, Rech-Weichsebraun et al is teaching an embodiment wherein the support or method does not require biotin/streptavidin (sensitivity enhancer). Although, Rech-Weichsebraun et al also discloses embodiments wherein biotin and streptavidin are used in the detection process, Rech-Weichsebraun et al also teaches the above embodiment of a third antibody labeled only with enzyme and the

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third antibody is specific for the second antibody (detection antibody). Also, one of ordinary skill in the art must consider all embodiments of a disclosure and it is well settled that a reference must be evaluated for all disclosures not just its preferred embodiments. *In re Mills*, 470 F. 2d 649, 176 USPQ 196 (CCPA 1972).

With respect to the incubation time of the stabilizer and the incubation time of the lyophilizing as recited in the instant claim, the optimum incubation times can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation.” *Application of Aller*, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation .” *Id.* At 458,105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” *Application of Boesch*, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

With respect to the pH range of the phosphate buffers as recited in instant claims 4 & 5, the optimum pH of phosphate buffer can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by



routine experimentation.” Application of *Aller*, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation .” *Id.* At 458,105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Application of *Boesch*, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

7. Claims 3, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Rech-Weichselbraun et al* in view of *Mitoma* and *Gatto-Menking et al* as applied to claims 1, 4, 5, 7-10, 16, 20 and 22-27 above, and further in view of *Rogan et al* (*Food Control*, 10, (1999), pgs 407-414).

See above for the teachings of *Rech-Weichsebraun et al.*, *Mitoma* and *Gatto-Menking et al.*

*Rech-Weichsebraun et al.*, *Mitoma* and *Gatto-Menking et al* differ from the instant invention in failing to teach the monoclonal antibody is against 5-enolpyruvylshikimate-3-phosphate synthase and the detection antibody (second antibody) is a IgG polyclonal antibody directed against 5-enolpyruvylshikimate-3-phosphate synthase.

*Rogan et al* disclose ELISA methods for the determination of 5-enolpyruvylshikimate-3-phosphate synthase protein in a sample. *Rogan et al* disclose the use of immobilized monoclonal antibody raised against 5-enolpyruvylshikimate-3-phosphate synthase (e.g. abstract, pgs. 408-409) to capture the 5-enolpyruvylshikimate-3-phosphate synthase and contacting captured 5-enolpyruvylshikimate-3-phosphate synthase with a polyclonal IgG detection antibody (second antibody) (abstract, pgs 408-409).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate capture and detection antibodies such as taught by Rogan et al into the modified method of Rech-Weichsebraun et al because Rech-Weichsebraun et al is generic with respect to the protein that is to be detected and one would use the appropriate reagents, i.e. capture and detection antibodies such as taught by Rogan et al to detect the desired protein, in this case 5-enolpyruvylshikimate-3-phosphate synthase.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rech-Weichselbraun et al in view of Mitoma and Gatto-Menking et al as applied to claims 1, 4, 5, 7-10, 16, 20 and 22-27 above, and further in view of Vogt et al (Journal of Immunological Methods, 101, (1987) pgs 43-50).

See above for the teachings of Rech-Weichsebraun et al., Mitoma and Gatto-Menking et al.

Rech-Weichsebraun et al., Mitoma and Gatto-Menking et al differ from the instant invention in failing to teach the blocker (stabilizer) used is a mixture of phosphate buffered saline.

Vogt et al teaches that it is known in the art to utilize fish gelatin diluted with phosphate buffer (as a blocking reagent (e.g abstract, p. 45, p. 48) (thus teaches mixture of phosphate buffered saline) and teaches that this mixture is an excellent blocker and is readily available without need for further processing (e.g. p. 49) and provides higher inhibition than that of BSA (Table II, pg 48).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a mixture of phosphate buffered saline and fish gelatin such as taught by Vogt et al for the BSA of Rech-Weichsebraun et al because Vogt teaches that fish gelatin is an excellent blocker and is readily available without need for further processing and provides higher inhibition than that of BSA in Elisa assays.

9. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rech-Weichselbraun et al in view of Mitoma, Gatto-Menking et and Rogan et al as applied to claims 1, 3-5, 7-10, 12, 13, 16, 20 and 22-27 above, and further in view of Padgett et al (Crop Science, 35: (1995), pgs 1451-1461).

See above for the teachings of Rech-Weichsebraun et al, Mitoma, Gatto-Menking et al., and Rogan et al.

Rech-Weichsebraun et al., Mitoma, Gatto-Menking et al and Rogan et al differ from the instant invention in failing to teach third antibody is obtained from the class Mammalia. Rech-Weichsebraun et al., Mitoma, Gatto-Menking et al and Rogan et al differ also fails to teach the enzyme is alkaline phosphatase and the substrate is para-nitrophenol.

Padgett et al discloses indirect Elisa methods for the detection of 5-enolpyruvylshikimate-3-phosphate synthase protein and teaches that it is known and conventional in the art to utilize a third antibody directed against the detection antibody and teaches that this antibody can is obtained from the class mammalia (e.g. p.1454) and is directed rabbit antibody (same secondary antibody as used by Rogan et al).

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Padgett et al also teaches that it is known and convention to utilize alkaline phosphatase as the enzyme and para-nitrophenyl phosphate as the substrate for this enzyme (p. 1454).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate donkey anti-rabbit alkaline phosphates antibodies and substrates such as taught by Padgett et al into the modified method of Rech-Weichsebraun et al because Padgett et al shows that such reagents are known and conventional in Elisa methods for the detection of 5-enolpyruvylshikimate-3-phosphate synthase and thus one of ordinary skill in the art would have a reasonable expectation of success incorporating donkey anti-rabbit alkaline phosphates antibodies and substrates such as taught by Padgett et al into the modified method of Rech-Weichsebraun et al.

### ***Response to Arguments***

10. Applicant's arguments filed 09/28/10 have been fully considered but they are not persuasive.

Applicant argues that the claimed support of the instant invention enables a user to perform ELISA in a single step within the short period of time of 150 minutes, which is remarkably shorter than the 250 minutes required in the prior art and also, that no additional reagent such as biotin and streptavidin are necessary to enhance the sensitivity of assays performed using the claimed support.

These arguments are not found persuasive because of reasons stated above that the combined teachings of Rech-Weichselbraun et al, Mitoma and Gatto-Menking et al

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teach the same support as instantly claimed comprising a first monoclonal antibody, stabilizer, second antibody and a third antibody labeled with enzyme. Therefore, it is deemed that the modified support of Rech-Weichselbraun et al enables a user to perform an ELISA in a single step within the time of 150 minutes. Further, with respect to the statement that no additional reagent such as biotin and streptavidin are necessary to enhance the sensitivity of the assays performed, as stated supra Rech-Weichselbraun et al teaches an embodiment wherein the microtiter wells comprise the first, second and third antibodies (see teachings supra) and specifically teaches that the second antibody (detection antibody) is specific for the analyte and teaches that the third antibody is labeled with enzyme and that this third antibody is specific for the detection antibody (see e.g. page 4, para 0046 "enzyme-coupled antibody against detection antibody"). Thus, Rech-Weichsebraun et al is teaching an embodiment wherein the support or method does not require biotin/streptavidin (sensitivity enhancer). Although, Rech-Weichsebraun et al also discloses embodiments wherein biotin and streptavidin are used in the detection process, Rech-Weichsebraun et al also teaches the above embodiment of a third antibody labeled only with enzyme and the third antibody is specific for the second antibody (detection antibody). Also, one of ordinary skill in the art must consider all embodiments of a disclosure and it is well settled that a reference must be evaluated for all disclosures not just its preferred embodiments. *In re Mills*, 470 F. 2d 649, 176 USPQ 196 (CCPA 1972).

Applicant further argues that the multiple proteins impregnated on the claimed support are stable and can be used at any time for ELISA and this stability of multiple

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proteins circumvents the problem of having to obtain conjugated or unconjugated antibodies from various sources.

This argument is not found persuasive because the combination of Rech-Weichselbraun et al, Mitoma and Gatto-Menking et al teach the same support as instantly claimed comprising the same antibodies and stabilizer as instantly claimed. Therefore, it is deemed that the modified support of Rech-Weichselbraun et al provides for stability of the antibodies (multiple proteins) and thus circumvents the problem of having to obtain conjugated or unconjugated antibodies from various sources.

Applicant argues that Rogan does not cure the deficiencies of Rech-Weichselbruan and Gatto-Menking et al. This argument is not found persuasive because of reasons stated above that Rech-Weichselbruan in light of Sawyer et al and in view of Mitoma and further in view of Gatto-Menking et al does not have deficiencies and the combination of Rogan with the above stated references is considered appropriate and therefore reads on the instantly recited claims.

Applicant argues that Vogt does not cure the deficiencies of Rech-Weichselbruan and Gatto-Menking et al. This argument is not found persuasive because of reasons stated above that Rech-Weichselbruan in light of Sawyer et al and in view of Mitoma and further in view of Gatto-Menking et al does not have deficiencies and the combination of Vogt with the above stated references is considered appropriate and therefore reads on the instantly recited claims.

Applicant argues that Padgett does not cure the deficiencies of Rech-Weichselbruan, Gatto-Menking et al., and Rogan. This argument is not found persuasive because of reasons stated above that Rech-Weichselbruan in light of Sawyer et al and in view of Mitoma and of Gatto-Menking et al., and Rogan does not have deficiencies and the combination of Padgett

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with the above stated references is considered appropriate and therefore reads on the instantly recited claims.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/  
Examiner, Art Unit 1641

/Melanie Yu/

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